Cidara Provides Corporate Update and Reports Second Quarter 2021 Financial Results

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SAN DIEGO, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (NASDAQ: CDTX), a biotechnology company developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections, today reported financial results for the second quarter ended June 30, 2021 and provided an update on its corporate activities and product pipeline.

“We began the quarter with the announcement of our worldwide license and collaboration agreement with Janssen for the development and commercialization of our Cloudbreak® influenza AVCs,” said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. “The global market for direct medical treatment of influenza is estimated to be up to $10.4 billion. This important partnership provides key external validation of the significant potential for our promising Cloudbreak program. We continue to anticipate filing an IND for our lead influenza candidate, CD388, by the end of 2021. Moreover, enrollment is progressing in both of our ongoing Phase 3 studies for rezafungin, and we continue to expect the availability of top-line data from the ReSTORE Phase 3 trial by year-end.”

Recent Corporate Highlights

- **Announced agreement with Janssen Pharmaceuticals for the development and commercialization of our influenza Antiviral Conjugates (AVCs), including CD388:** In March, Cidara entered into a worldwide license and collaboration agreement with Janssen Pharmaceuticals, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize Cidara’s Cloudbreak AVCs for the prevention and treatment of seasonal and pandemic influenza. Under the terms of the collaboration, Cidara received an upfront payment of $27 million and will be eligible for reimbursement of up to $58 million in research and development costs incurred in conducting Research Plan activities. The Company will also be entitled to receive up to an additional $695 million in development, regulatory and commercial milestone payments, as well as royalties on tiers of annual net sales of Products at rates from the mid-single digits to the high-single digits. Janssen will fund all future research, development, manufacturing and commercialization for CD388.

- **Presented at Mycology 2021 Conference:** In June, Cidara presented highlights from pre-clinical through Phase 2 clinical trial data evaluating rezafungin for the treatment and prevention of invasive fungal disease at the Mycology 2021 Conference.

- **Participated in Raymond James Human Health Innovation Conference:** In June, Cidara participated in investor meetings at the Raymond James Human Health Innovation Conference.

- **Presented at 31st European Congress of Clinical Microbiology and Infectious Diseases (ECCMID):** In July, Cidara presented new analyses from multiple studies of rezafungin for the treatment of candidemia and invasive candidiasis and prevention of invasive fungal infections at ECCMID. Cidara’s oral presentation reviewed a new sub-analysis from the STRIVE Phase 2 trial demonstrating clearance of infection in the initial days of treatment of candidemia following one dose of rezafungin, compared to multiple doses of the standard of care. Three additional posters at ECCMID highlighted areas of unmet need to improve treatment of candidemia and invasive candidiasis.

Second Quarter 2021 Financial Results

- Revenue totaled $32.9 million and $35.3 million for the three and six month periods ended June 30, 2021, compared with $3.4 million and $5.9 million for the same periods of 2020. The increase was primarily attributable to the revenue recognized in connection with Cidara's recently announced collaboration with Janssen Pharmaceuticals.

- Cash, cash equivalents and restricted cash totaled $53.1 million as of June 30, 2021, compared with $42.9 million as of December 31, 2020.

- As of June 30, 2021, Cidara had 49,506,268 shares of common stock outstanding, and 1,044,278 shares of Series X convertible preferred stock outstanding, which are convertible into 10,442,780 shares of common stock.

- Research and development expenses were $17.7 million and $33.6 million for the three and six month periods ended June 30, 2021, compared to $17.6 million and $30.6 million for the same periods in 2020.

- General and administrative expenses were $4.4 million and $9.2 million for the three and six month periods ended June 30, 2021, compared to $4.0 million and $8.1 million for the same periods in 2020.

- Net income for the three months ended June 30, 2021 was $10.7 million, compared to a net loss of $18.3 million for the same period in 2020. For the six months ended June 30, 2021 and 2020, net loss was $7.6 million and $32.8 million, respectively.

About Cidara Therapeutics
Cidara is developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections. The Company's portfolio is comprised of its lead antifungal candidate, rezafungin, in addition to AVCs for the prevention and treatment of influenza and other viral diseases from Cidara's proprietary Cloudbreak® antiviral platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements
This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to our plans to file an IND for CD388 and receive top-line data for the Phase 3 ReSTORE trial by the end of 2021, and the receipt of payments under the Janssen agreement. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, such as unanticipated delays in or negative results from Cidara's pre-clinical or clinical trials, impacts of the COVID-19 pandemic or other obstacles to the development of CD388. These and other risks are identified under the caption "Risk Factors" in Cidara's most recent Quarterly Report on Form 10-Q and other filings subsequently made with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Cidara does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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CIDARA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except share and per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Collaboration revenue	$ 32,863	$ 3,392	$ 35,271	$ 5,922
Total revenues	32,863	3,392	35,271	5,922
Operating expenses:				
Research and development	17,720	17,634	33,569	30,630
General and administrative	4,370	3,969	9,151	8,064
Total operating expenses	22,090	21,603	42,720	38,694
Income (loss) from operations	10,773	(18,211)	(7,449)	(32,772)
Other expense:				
Interest expense, net	(62)	(95)	(132)	(73)
Total other expense, net	(62)	(95)	(132)	(73)
Net income (loss) and comprehensive income (loss)	10,711	(18,306)	(7,581)	(32,845)
Allocation of earnings to participating securities	(1,892)	—	—	—
Recognition of beneficial conversion feature	—	—	—	(2,762)
Net income (loss) attributable to common shareholders	$ 8,819	$ (18,306)	$ (7,581)	$ (35,607)
Basic net earnings (loss) per common share	$ 0.18	$ (0.45)	$ (0.16)	$ (0.90)
Diluted net earnings (loss) per common share	$ 0.18	$ (0.45)	$ (0.16)	$ (0.90)
Shares used to compute basic net earnings (loss) per common share	48,677,008	40,965,180	47,826,812	39,410,751
Shares used to compute diluted net earnings (loss) per common share	59,323,220	40,965,180	47,826,812	39,410,751

Condensed Consolidated Balance Sheet Data

(In thousands)	June 30, 2021 (unaudited)	December 31, 2020
Cash, cash equivalents, and restricted cash	$ 53,099	$ 42,949
Total assets	63,744	60,424
Term loan	4,808	7,023
Total liabilities	47,955	49,709
Total stockholders' equity	15,789	10,715